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U.S. PTO

430 Rec'd PCT/PTO 15 APR 1999

PCT

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

09/284684

Attorney's Docket Number: 1620/3
U.S. Application No. _____

International Application No.: PCT/GB97/02863
Priority Date Claimed: October 17, 1996
Title of Invention: VITAMIN DELIVERY
Applicant: PLUMMER, Nigel, Terrence

International Filing Date: October 17, 1997
Express Mail Label No.: EL121024606US

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. XX This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. XX This express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1)).
4. XX A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
- XX A copy of the International Application filed (35 U.S.C. 371 (c)(2)).
 - a. is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. X has been transmitted by the International Bureau.
 - c. is not required, as the application was filed in the United States Receiving Office (RO/US).
- A translation of the International Application into English (35 U.S.C. 371(c)(2)).
- XX Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. XX are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. have been transmitted by the International Bureau
 - c. have not been made; however, the time limit for making such amendments has NOT expired.
 - d. have not been made and will not be made.
- A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
- XX A **COPY** of an Oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). **(unsigned)**
- A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. An Information Disclosure statement under 37 C.F.R. 1.97 and 1.98.
12. An Assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. XX A **FIRST** Preliminary Amendment.
 A **SECOND** or **SUBSEQUENT** Preliminary Amendment.
14. A substitute specification.
15. A change of Power of Attorney and/or address letter.
16. XX Other items or information: **IEPR (copy)**

17. XX The following fees are submitted:

CALCULATIONS

Basic National Fee (37 C.F.R. 1.492(a)(1)-(5):

Search Report has been prepared by the EPO and JPO	\$ 840.00	\$ 840.00
International preliminary examination fee paid to		
U.S. P.T.O. (37 C.F.R. 1.482)	\$ 720.00	\$
No International preliminary examination fee paid to		
U.S. P.T.O. (37 C.F.R. 1.482) but international search fee		
paid to U.S. P.T.O. (37 C.F.R. 1.445(a)(2))	\$ 790.00	\$
Neither international preliminary examination fee		
(37 C.F.R. 1.482) nor international search fee (37 C.F.R.		
1.445(a)(2)) paid to U.S. P.T.O	\$1,070.00	\$
International preliminary examination fee paid to U.S.		
P.T.O. (37 C.F.R. 1.482) and all claims satisfied provisions		
of PCT Article 33(2)-(4)	\$ 98.00	\$
ENTER APPROPRIATE BASIC FEE AMOUNT		\$ 840.00

Surcharge of \$130.00 for furnishing the oath or declaration later than 20 X 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).

Claims	Number Filed	Number Extra	Rate	
Total Claims	20	-20	0	x 18.00 \$ 0.00
Independent Claims	2	-3	0	x 78.00 \$ 0.00
Multiple Dependent claim(s) (if applicable)				x 270.00 \$ 0.00
TOTAL OF ABOVE CALCULATIONS:				\$ 970.00

Reduction by 1/2 for filing by small entity, if applicable. Verified Statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)

(Applicant entitled to SE status - Verified Statement to follow under separate cover.)

SUBTOTAL:		\$ 485.00
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Processing fee of \$130.00 for furnishing the English translation later the 20 30 months from the earliest claimed priority date (37 C.F.R. 1.492(f)).

TOTAL NATIONAL FEE:		\$ 485.00
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Fee recording the enclosed Assignment (37 C.F.R. 1.21(h)). The Assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property \$

TOTAL FEE ENCLOSED:		\$ 485.00
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a. XX A check in the amount of \$ 485.00 to cover the above fees is enclosed.

b. — Please charge my Deposit Account No. 01-0265 in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. XX The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 01-0265. A duplicate copy of this sheet is enclosed.

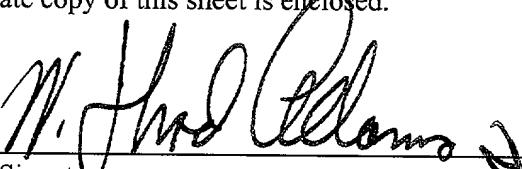
SEND ALL CORRESPONDENCE TO:

ADAMS LAW FIRM, P.A.

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Charlotte, North Carolina 28282

(704) 375-9249


Signature

W. Thad Adams, III Reg. No. 29,037

Name and Registration No.

Date: April 15, 1999

09/284684

571001 PCT/GB97/02863

15 APR 1999

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: PLUMMER, Nigel, Terrence

INTERNATIONAL
APPLICATION NO.: PCT/GB97/02863

INTERNATIONAL
FILING DATE: October 17, 1997

FOR: VITAMIN DELIVERY

BOX PCT
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

After the assignment of a serial number and prior to the initial examination of the above-identified patent application, please make the following amendments:

IN THE CLAIMS:

Cancel original Claims 1 - 21.

Enter new Claims 1 - 18 as follows:

1. A method of preparing a vitamin for delivery to a subject, comprising the steps of:
 - (a) adding least one vitamin to a wet carrier to form an ingestible mix; and
 - (b) freeze-drying the ingestible mix.
2. A method according to Claim 1, wherein the at least one vitamin is in solubilised form

O B E G E E M T P A T E M E N T

3. A method according to Claim 1, wherein the wet carrier is a natural material.
4. A method according to Claim 3, wherein the wet carrier is formed from fruit.
5. A method according to Claim 3, wherein the wet carrier comprises a fruit product selected from the group consisting of fruit juice and fruit pulp.
6. A method according to Claim 1, wherein the at least one vitamin comprises two or more vitamins.
7. A method according to Claim 1, and including the step of calculating the amount of vitamin to add to the carrier by reference to the vitamin content or concentration required in the freeze-dried product.
8. A method according to Claim 1, and including the step of freeze-drying the mix in discrete units.
9. A method according to Claim 1, and including the step of choosing the vitamin concentration in the mix which will provide in each freeze-dried unit a predetermined dose of vitamin.
10. A method according to Claim 9, wherein the predetermined dose is a recommended daily allowance or simple fraction thereof.
11. A vitamin delivery product comprising an ingestible freeze-dried mix of at least one vitamin and an ingestible carrier.
12. A product according to Claim 11, wherein the carrier is a natural material.

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13. A product according to Claim 12, wherein the carrier is formed from fruit.
14. A product according to Claim 12, wherein the carrier is produced from a fruit product selected from the group consisting of fruit juice and fruit pulp.
15. A product according to Claim 11 and comprising a blend of vitamins.
16. A product according to Claim 11 wherein the mix comprises freeze-dried discrete units.
17. A product according to Claim 16, wherein each unit incorporates a predetermined dose of vitamin.
18. A product according to Claim 17, wherein each unit incorporates a recommended daily allowance.

REMARKS

It is believed that this application is now in condition for allowance. Such action at an early date is respectfully requested.

DATED: April 15, 1999

Respectfully submitted,



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1620&3.pre

1
Vitamin Delivery

The present invention relates to vitamin delivery and particularly, but not exclusively, to the preparation of vitamins for delivery to subjects on a voluntary basis without medical prescription.

It is well recognised that various deficiency disorders can arise if vitamin intake is not adequate and for this reason, the health authorities in many countries specify recommended daily allowances (RDAs) of various vitamins for children and adults. Vitamins can be delivered to the subject in a number of ways. The most common form is for a discrete dosage to be ingested in tablet form or by hard or soft gelatine capsules, or by means of powders or liquids. Another common technique of delivering vitamins is by "fortifying" food or beverage products with additional prophylactic components such as vitamins. These food and beverage products may be soft drinks, cereals, dairy products, fruit juices or confectionery.

Capsules, tablets and other discrete dosage forms have the disadvantage that bulking agents (or excipients) are usually required in order to produce a tablet which is sufficiently large for convenient handling and storage. In consequence, the subject taking the capsule or tablet will ingest a considerable amount of bulking agent (which is wholly unnecessary to the prophylactic purpose) along with the desired vitamin content.

For marketing to children in particular, various fruit flavourings, natural colours and fruit powders have been used to produce tablets which are more palatable and therefore more likely to be used with adequate regularity, but considerable volumes of excipient are required.

The present invention seeks to improve vitamin delivery.

The invention provides a method of preparing a vitamin for delivery to a subject, in which at least one vitamin is added to a wet carrier to form a mix which is subsequently freeze-dried, the freeze-dried mix being ingestible.

The term "wet" is used to indicate a form which incorporates more than a negligible amount of water, e.g. a form in which water can be extracted by a freeze-drying process. Preferably the vitamin or vitamins are in solubilised form. Some vitamins are soluble in water; others require treatment to allow emulsification for dispersal in water. Vitamin mixtures are commercially available which contain soluble vitamins and treated insoluble vitamins. The term solubilised is used herein to encompass soluble vitamins, treated insoluble vitamins and mixtures of these.

The wet carrier is preferably a natural material and may be formed from fruit. The wet carrier may comprise fruit juice and/or fruit pulp.

A blend of vitamins may be added as aforesaid. The amount of vitamin added to the carrier may be calculated by reference to the vitamin content or concentration required in the freeze-dried product.

Preferably the mix is freeze-dried in discrete units. The vitamin concentration in the mix is preferably chosen to cause each freeze-dried unit to incorporate a predetermined dose of vitamin. The predetermined dose may be a recommended daily allowance or simple fraction thereof.

The invention also provides a vitamin delivery product comprising an ingestible freeze-dried mix of at least one vitamin and a carrier.

The carrier is preferably a natural material and may be formed from fruit. The carrier may be formed from fruit juice and/or fruit pulp.

Preferably the product comprises a blend of vitamins. The mix is preferably freeze-dried in discrete units, with each unit preferably incorporating a predetermined dose of vitamin, such as a recommended daily allowance.

The present invention will now be described in more detail, by way of example only, and with reference to the accompanying drawings, in which:-

Fig. 1 is a highly schematic diagram illustrating a first stage of a method according to the invention; and

Fig. 2 illustrates a later stage of the method of Fig. 1.

The method to be described is for preparing a vitamin for delivery to a subject, such as a human, and is particularly applicable to vitamin supplements for delivery on a voluntary basis, without medical supervision, such as vitamin delivery products intended to provide a recommended daily allowance of one or more vitamins.

In order to produce the product, a wet carrier is first produced (indicated at 10 in Fig. 1) and introduced into a mixing vessel 12. The wet carrier is preferably a natural material which may be formed from fruit. It is envisaged that fresh or frozen fruit can be formed into a puree or (by removal of fruit pulp) juice to serve as the wet carrier. Typical fruit pulps will have a dry solids content of approximately 10% to 13%, while typical fruit juice will have a dry solids content of approximately 5% to 10%. Concentrates with higher solids contents could be used. The wet carrier 10 is introduced into the mixing vessel 12.

A vitamin or mixture of vitamins is then formed (indicated at 14 in Fig. 1) in a solubilised form and added to the wet carrier already in the mixing vessel 12. Naturally the sequence can be reversed, but it is envisaged that the volume of carrier will exceed the volume of vitamin material and thus that mixing will be facilitated by the introduction of vitamin into the carrier, rather than vice versa.

The contents of the vessel 12 are then mixed to a homogeneous mixture, with agitation or other mixing technique. The solubilised form of the vitamin content enhances the homogeneity of the mixture.

The homogeneous mixture so formed is then dispensed from the vessel 12 into individual cavities 16 of a mould tray 18 (Fig. 2). This task of

dispensing is illustrated schematically by means of a pipette 20 but any alternative arrangement appropriate to the nature of the material and volumes to be dispensed could be used.

The contents of the tray 18 are then freeze-dried to substantially remove the water content thereof. Since freeze-drying involves minimal shrinkage of the dry solids content of the mix, the result is a block of dried material in each mould 16 and having the shape and size of the packet of liquid originally introduced into the mould 16. These dried units can then be removed from the moulds and packaged in an appropriate manner, such as in blister packs for retail sale as a vitamin supplement.

The vitamin delivery product so produced will contain only the dried fruit and vitamin, without excipient. Its taste will be virtually wholly determined by the original fruit content of the carrier 10. This is expected to provide a palatability and mouth feel which are greatly improved over known vitamin supplements and similar products, so that the product described is expected to be well received in the children's market.

It is preferred that each dried unit contains a recommended daily allowance of the vitamin or vitamin blend, or a simple fraction thereof (such as a half, quarter etc.).

The concentration of vitamins required in the mix formed in the vessel 12 can be calculated as follows. First, the vitamin dose to be delivered by each unit is chosen. This might, for instance, be 100mg. Secondly, the volume of the final unit is chosen (perhaps 1ml), largely for practical reasons of handling and user preference. The mix in the vessel 12 is thus required to have a vitamin concentration of one dose per final unit volume. Other factors may influence final choices. For instance, some vitamins have stronger or more unpleasant tastes than others, requiring a higher ratio of fruit content to vitamin content to disguise the vitamin taste. The final unit volume might therefore be increased to assist in this way. The dry solids content of the fruit

component also affects the final product, in that a material with a higher dry solids content is more likely to adequately mask a vitamin taste, than would a material with a lower dry solids content. These factors may affect the choice of fruit material (e.g. the fruit type) or the form (juice, fruit pulp, concentrate etc.). The mouth feel and taste are affected by these choices. A final product can be produced which consists of a honeycomb structure of dried fruit solid, through which the vitamin dose is evenly distributed, and which has an acceptable taste and texture in the mouth.

It is expected that the technique can be applied to a wide variety of natural materials, particularly a wide variety of fruit juices and pulps, and to many different vitamins and vitamin blends, so that a wide range of vitamin delivery products can be produced for many different purposes.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

CLAIMS

1. A method of preparing a vitamin for delivery to a subject, in which at least one vitamin is added to a wet carrier to form a mix which is subsequently freeze-dried, the freeze-dried mix being ingestible.
2. A method according to Claim 1, wherein the vitamin or vitamins are in solubilised form.
3. A method according to Claim 1 or 2, wherein the wet carrier is a natural material.
4. A method according to Claim 3, wherein the wet carrier is formed from fruit.
5. A method according to Claim 3 or 4, wherein the wet carrier comprises fruit juice and/or fruit pulp.
6. A method according to any preceding claim, wherein a blend of vitamins is added as aforesaid.
7. A method according to any preceding claim, wherein the amount of vitamin added to the carrier is calculated by reference to the vitamin content or concentration required in the freeze-dried product.
8. A method according to any preceding claim, wherein the mix is freeze-dried in discrete units.
9. A method according to any preceding claim wherein the vitamin concentration in the mix is chosen to cause each freeze-dried unit to incorporate a predetermined dose of vitamin.
10. A method according to claim 9, wherein the predetermined dose is a

recommended daily allowance or simple fraction thereof.

11. A vitamin delivery product comprising an ingestible freeze-dried mix of at least one vitamin and a carrier.

12. A product according to claim 11, wherein the carrier is a natural material.

13. A product according to Claim 12, wherein the carrier is formed from fruit.

14. A product according to Claim 12 or 13, wherein the carrier is formed from fruit juice and/or fruit pulp.

15. A product according to any of Claims 11 to 14, comprising a blend of vitamins.

16. A product according to any of Claims 11 to 15, wherein the mix is freeze-dried in discrete units.

17. A product according to Claim 16, wherein each unit incorporates a predetermined dose of vitamin.

18. A product according to Claim 17, wherein each unit incorporates a recommended daily allowance.

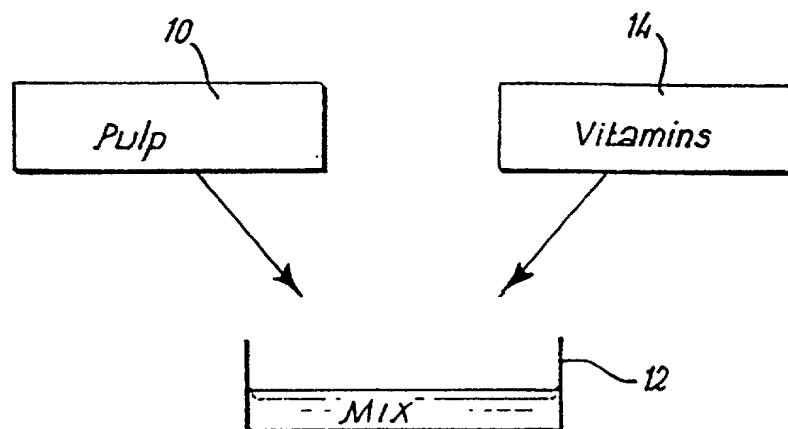


FIG. 1

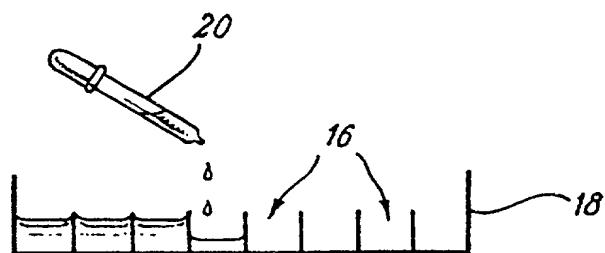


FIG. 2

**COMBINED DECLARATION FOR PATENT APPLICATION AND
POWER OF ATTORNEY**
(Includes Reference to PCT International Applications)

Attorney's Docket Number

F-6185

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

ROBOT VEHICLE FOR HOT-LINE JOB

the specification of which (check only one item below):

is attached hereto.

was filed as United States application
Serial No. _____
on _____,
and was amended
on _____ (if applicable).

was filed as PCT international application
Number **PCT/JP97/03734**,
on **October 16, 1997**
and was amended under PCT Article 19
on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

Country (if PCT indicate "PCT")	Application Number	Date of Filing (day, month, year)	Priority Claimed Under 35 USC 119
Japan	8-276671	October 18, 1996	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No
			<input type="checkbox"/> Yes <input type="checkbox"/> No

**COMBINED DECLARATION FOR PATENT APPLICATION AND
POWER OF ATTORNEY (Continued)**

(Includes Reference to PCT International Applications)

Attorney's Docket Number

F-6185

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:				
U.S. APPLICATIONS			STATUS (Check One)	
U.S. Application Number	U. S. Filing Date		Patented	Pending
PCT APPLICATIONS DESIGNATING THE U.S.				
PCT Application No.	PCT Filing Date	U.S. Serial Numbers Assigned (if any)		

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Frank J. Jordan Reg. No. 20,456
C. Bruce Hamburg Reg. No. 22,389
Lainie E. Parker Reg. No. 36,123

Herbert F. Ruschmann Reg. No. 35,341
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Send Correspondence To:	<u>Jordan and Hamburg</u> <u>122 East 42nd Street</u> <u>New York, New York 10168</u>	Direct Telephone Calls to: C. Bruce Hamburg (212) 986-2340
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full Name of Sole or First Inventor (1) Hirofumi INOKUCHI	Inventor's Signature <i>Hirofumi Inokuchi</i>	Date
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9-00

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10-00

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14-00

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15-62

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Post Office Address SAME AS (1) ABOVE		

16-02

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17-03

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18-01

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19-02

Full Name of Nineteenth Joint Inventor, if any <u>Osamu YAMASHITA</u>	Inventor's Signature <u>Osamu Yamashita</u>	Date
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Post Office Address c/o Kyushu Electri Power Co., Inc., 1-82 Watanabe-dori 2-chome, Chuo-ku, Fukuoka-shi, Fukuoka, 810-0004 Japan		